## CLAIMS

1. A vaccine for inducing an immune response in a mammal against at least one pathogenic microorganism, wherein the vaccine is formulated for administration to mucosa of the lungs of the mammal and comprises a cellular fraction of the microorganism that is essentially free of particulate matter and includes polyvalent soluble antigen from the microorganism, together with a pharmaceutically acceptable carrier.

2. A vaccine according to claim 1 wherein the cellular fraction comprises cellular matter and the polyvalent soluble antigen.

3. A vaccine according to claim 1 or 2 wherein the vaccine is formulated without any added adjuvants.

4. A vaccine according to claim 1 or 2 wherein the vaccine is formulated with one or more added adjuvants.

5. A vaccine according to claim 4 wherein the adjuvant is selected to promote a Th1 T-cell immune response and/or to suppress a Th2 T-cell immune response in the mammal.

6. A vaccine according to any one of claims 1 to 5 wherein the cellular fraction is prepared from the whole said microorganism.

7. A vaccine according to any one of claims 1 to 6 wherein the cellular fraction is a sonicate.

8. A vaccine according to any one of claims 1 to 7 wherein the cellular fraction is filterable through a filter with a pore size of less than 0.60 μm.

9. A vaccine according to claim 8 wherein the pore size is less than 0.20 μm.

10. A vaccine according to any one of claims 1 to 9 wherein the microorganism is a microorganism that colonises the lung or respiratory tract.

11. A vaccine according to any one of claims 1 to 10 wherein the protective immune response is a systemic immune response.

12. A vaccine according to any one of claims 1 to 11 for the prophylaxis or treatment of an infection by the microorganism selected from the group consisting of lung, oral, nasal, oropharyngeal, nasalpharyngeal, pharyngeal, respiratory tract, digestive tract, vaginal, urinary tract, kidney, eye and skin infections.

13. A vaccine according to claim 12 wherein the infection is a lung or respiratory tract infection.

14. A vaccine according to any one of claims 1 to 11 wherein the microorganism is a bacterial, fungal or yeast pathogen.

15. A vaccine according to claim 14 wherein the microorganism is a bacterial pathogen selected from the group consisting of *Non-typeable H. influenzae, Moraxella catarrhalis, S. pneumoniae, P. aeruginosa, H. influenzae* type b, *H. pylori, S. aureus, S. albus, C. pneumoniae, C. trachomatis, S. pyrogenes, E. coli* species and *Mycoplasma* species.

16. A vaccine according to claim 15 wherein the bacterial pathogen is selected from *Non-typeable H. influenzae, S. pneumoniae* and *P. aeruginosa.*

17. A method for prophylaxis or treatment of an infection in a mammal by at least one pathogenic microorganism, the method comprising administering an effective amount of a cellular fraction of the microorganism to mucosa of the lungs of the mammal for generating an immune response against the microorganism, wherein the cellular fraction is essentially free of particulate matter and includes polyvalent soluble antigen from the microorganism.

18. A method according to claim 17 wherein the cellular fraction comprises cellular matter and the polyvalent soluble antigen.

19. A method according to claim 17 or 18 wherein the vaccine is formulated without any added adjuvants.

20. A method according to claim 17 or 18 wherein the vaccine is formulated with one or more added adjuvants.

21. A method according to claim 20 wherein the adjuvant is selected to promote a Th1 T-cell immune response and/or to suppress a Th2 T-cell immune response in the mammal.

22. A method according to any one of claims 17 to 21 wherein the cellular fraction is prepared from the whole said microorganism.

23. A method according to any one of claims 17 to 21 wherein the cellular fraction is a sonicate.

24. A method according to any one of claims 17 to 23 wherein the cellular fraction is filterable through a filter with a pore size of less than 0.60 μm.

25. A method according to claim 24 wherein the pore size is about 0.20 μm or less.

26. A method according to any one of claims 17 to 25 wherein the microorganism is a microorganism that colonises the lung or respiratory tract.

27. A method according to any one of claims 17 to 26 wherein the immune response is a systemic immune response.

28. A method according to any one of claims 17 to 27 for the prophylaxis or treatment of an infection by the microorganism selected from the group consisting of lung, oral, nasal, oropharyngeal, nasalpharyngeal, pharyngeal, respiratory tract, digestive tract, vaginal, urinary tract, kidney, eye and skin infections.

29. A method according to claim 28 wherein the infection is a lung or respiratory tract infection.

30. A method according to any one of claims 17 to 27 wherein the microorganism is a bacterial, fungal or yeast pathogen.

31. A method according to claim 30 wherein the microorganism is a bacterial pathogen selected from the group consisting of *Non-typeable H. influenzae, Moraxella catarrhalis, S. pneumoniae, P. aeruginosa, H. influenzae* type b, *H. pylori, S. aureus, S. albus, C. pneumoniae, C. trachomatis, S. pyrogenes, E. coli* species and *Mycoplasma* species.

32. A method according to claim 31 wherein the bacterial pathogen is selected from *Non-typeable H. influenzae, S. pneumoniae* and *P. aeruginosa.*

33. A method for prophylaxis or treatment of a disease or condition in a mammal associated with, or exacerbated by, infection by at least one pathogenic microorganism, the method comprising administering an effective amount of a cellular fraction of the microorganism to mucosa of the lungs of the mammal for generating an immune response against the microorganism, wherein the cellular fraction is essentially free of particulate matter and includes polyvalent soluble antigen from the microorganism.

34. A method according the claim 33 wherein the cellular fraction comprises cellular matter and the polyvalent soluble antigen.

35. A method according to claim 33 or 34 wherein the vaccine is formulated without any added adjuvants.

36. A method according to claim 33 or 34 wherein the vaccine is formulated with one or more added adjuvants.

37. A method according to claim 36 wherein the adjuvant is selected to promote a Th1 T-cell immune response and/or to suppress a Th2 T-cell immune response in the mammal.

38. A method according to any one of claims 33 to 37 wherein the cellular fraction is prepared from the whole said microorganism.

39. A method according to any one of claims 33 to 38 wherein the cellular fraction is a sonicate.

40. A method according to any one of claims 33 to 39 wherein the cellular fraction is filterable through a filter with a pore size of les than 0.60 μm.

41. A method according to claim 40 wherein the pore size is less than 0.20 μm.

42. A method according to any one of claims 33 to 41 wherein the microorganism is a microorganism that colonises the lung or respiratory tract.

43. A method according to any one of claims 33 to 42 wherein the immune response is a systemic immune response.

44. A method according to any one of claims 33 to 43 wherein the infection is an infection of the lung or respiratory tract.

45. A method according to any one of claims 33 to 44 wherein the microorganism is a bacterial pathogen.

46. A method according to claim 45 wherein the bacterial pathogen is selected from the group consisting of *H. influenzae type b, Non-typeable H. influenzae, S. pneumoniae* and *P. aeruginosa.*

47. A method according to any one of claims 33 to 46 wherein the disease or condition is selected from the group consisting of otitis media, pneumonia, chronic bronchitis, cystic fibrosis, asthma, lung conditions and superinfections following viral infection.